REMARKS

With this response, claims 1-3, 5-12, 14-21 are pending. Claim 1 has been amended without prejudice or disclaimer, and claim 13 has been canceled without prejudice or disclaimer by way of the present amendment. It is noted that claims 7 and 15-21 have been withdrawn as directed to a non-elected invention. Regardless, Applicants reserve the right to prosecute the non-elected invention in a continuing application. Support for the foregoing amendment can be found throughout the specification and the claims as originally filed, for example, in the Specification at page 6, lines 3 - 12; page 15, lines 5 - 10; and page 17, lines 5-11.

I. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-3, 5-6, and 8-13 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Office Action at page 4.

In support of this rejection, the Examiner alleges that "[t]he specification fails to provide any critical structural feature to adequately describe the genus of PYY agonists that may be administered in the claimed method. The specification merely discloses two compounds, a human PYY of SEQ ID NO: 2 and PYY (3-36) of SEQ ID: NO: 3, which are not sufficiently representative of the genus of PYY agonists." Office Action at page 5. The Examiner goes on to state that "only the method of administering PYY and PYY (3-36), but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph." Office Action at pages 5-6. Applicants respectfully disagree with these assertions.

The standard for determining whether a claim drawn to a genus meets the written description requirement is clear. "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice . . . , reduction to drawings . . . , or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in

possession of the claimed genus." *See Regents of the University of California v. Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406; M.P.E.P § 2163(II)(3)(a)(ii) (emphasis added). A "representative number of species" means that the species which are adequately described are representative of the entire genus. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. *Id.* Applicants have met this burden.

The instant specification provides numerous PYY agonist and analog species that are representative of the claimed genus. Specification at page 18, line 28 - page 28, line 2. For example, a wide-range of deletions, substitutions, or insertions may be made to the amino acid sequences of PYY to generate PYY mutants with activity. Specification at page 21, line 8 - page 22, line 10. Moreover, the present application teaches how PYY agonists may be specifically developed, identified, and characterized. Specification at page 24, line 16 - page 28, line 2. In short, Applicants submit that the claimed genus is fully supported by the specification.

Further written description support for the claimed species can be found in the numerous patents and journal articles that are incorporated by reference in the specification. For example, US 5,604,203, a patent incorporated by reference in the instant specification, provides thousands of possible PYY agonist and analog species that are representative of the claimed genus. In meeting the written description requirement, "information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed." MPEP 2163.07(b). This provides further support that Applicants were in possession of the claimed genus at the time the application was filed.

Applicants have provided sufficient guidance and working examples as to structural and functional characterization of the claimed PYY agonists, *e.g.*, through extensive disclosure of PYY analog sequences, and/or assays for verifying PYY activity. Specification at page 18, line 28 - page 28, line 2. Accordingly, Applicants submit that PYY agonists and agonist analogs, including derivatives, are sufficiently described in the specification to reasonably convey to one of ordinary skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants respectfully submit that one skilled in the art would readily appreciate that Applicants, at the time of the filing of the present application, were in possession of the claimed

genus and, therefore, have met the written description requirement. As such, it is submitted that the claims comply with 35 U.S.C. §112, first paragraph, and withdrawal of this rejection is respectfully requested.

II. Rejections under 35 U.S.C. § 102

A. Rejections over El-Salhy *et al.* (Peptides 23:397-402, February 2002)

In rejecting claims 1-3, 5, 10, and 13[1], the Examiner asserts that El-Salhy *et al.* "teach a decreased level of PYY in human patients with gastrointestinal disorders, including inflammatory bowel diseases." Office Action at page 6. Moreover, the Examiner contends that "El-Salhy et al. further teach that infusion of PYY in dogs increases colonic absorption of water, Na and Cl ions and PYY or its analogue can be of use as clinical agents in intestinal malabsorption disorders or after bowel resection." *Id.* Applicants respectfully disagree.

In order for a claim to be anticipated, a reference must teach every element of the claim. MPEP § 2131. That is, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

El-Salhy *et al.* does not disclose a method of treating intestinal damage comprising administering a pharmaceutically active formulation of PYY or PYY agonist to a human. The administration of PYY to any subject is speculated upon in only one sentence of El-Salhy *et al.* El-Salhy *et al.* at page 401, lines 23-26. In this sentence, it was noted that "infusion of PYY in dogs increases colonic absorption of water, Na, and Cl ions [38][2], and intraluminal administration of a synthetic analog, BIM-34004, has the same effect [39][3]." *Id.* As such, El-Salhy *et al.* clearly does not teach administration of PYY or PYY agonists to a subject, let alone a human. Rather, El-Salhy *et al.* merely paraphrases two references. *Id.*

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[1] Claims 2-3, 5, 10, and 13 depend from claim 1.

[2] Liu *et al.*, *Am. Surg.* **62**, 232-236 (1996).

[3] Liu *et al.*, *J. Surg. Res.* **59**, 80-84 (1995).

Moreover, El-Salhy *et al.* does not teach or fairly suggest administering PYY to any subject in order to treat intestinal damage, let alone damage associated with inflammatory bowel disease, bowel atrophy, loss of bowel mucosa, loss of bowel mucosal function, or ulcerative colitis. At best, El-Salhy *et al.* could be argued to suggest that "infusion of PYY in dogs increases colonic absorption of water, Na, and Cl ions." *Id.* This is not anticipation of the presented claims. Nonetheless, to facilitate prosecution, Applicants have also amended claim 1 to recite the term "human."

In light of the above, Applicants respectfully request that the Examiner withdraw the rejections.

B. Rejections over U.S. Patent No. 5,604,203 (Balasubramaniam *et al.*)

The Examiner asserts that Balasubramaniam *et al.* meets the limitations of claims 1-2, 5, 10-12[4]. Office Action at page 7. In support of this contention, the Examiner alleges that Balasubramaniam *et al.* teaches treating gastrointestinal disorders by orally administering PYY and functional analogs. Applicants respectfully disagree.

Balasubramaniam *et al.* does not teach or even fairly suggest administering PYY or a PYY agonist to a human. Moreover, Balasubramaniam *et al.* does not teach or fairly suggest administering PYY to a subject in order to treat intestinal damage. As such, withdrawal of this rejection is respectfully requested.

C. Rejections over Yoshinaga *et al.* (Am J. Physiol. 263: G695 -701, 1992)

The Examiner asserts that Yoshinaga *et al.* meets the limitations of claims 1, 10, and 14[5]. Office Action at page 7. In support of this contention, the Examiner alleges that Yoshinaga *et al.* teach a method of inhibiting pancreatic exocrine and gastric acid output comprising administration of PYY and a PYY agonist [3-36] to a subject. *Id.* Applicants respectfully disagree.

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[4] Claims 2, 5, and 10-12 depend from claim 1.

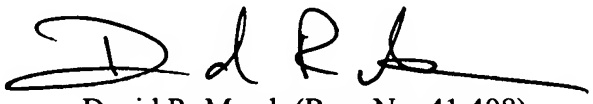
[5] Claims 10 and 14 depend from claim 1.

Whatever else Yoshinaga *et al.* discloses or even suggests it fails to disclose or suggest a method of treating intestinal damage by administering a pharmaceutically active formulation of PYY or a PYY agonist to a human. As such, Yoshinaga *et al.* does not anticipate the claimed invention and Applicants respectfully request withdrawal of the rejection.

Conclusion

In view of the foregoing arguments and amendments, each of the presently pending claims is believed to be in immediate condition for allowance. All of the stated grounds of rejection or objection have been traversed, accommodated, or rendered moot. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and objections and to pass this application to issue. The Examiner is encouraged to contact the undersigned at 202.942.5068 should any additional information be necessary for allowance.

Respectfully submitted,



David R. Marsh (Reg. No. 41,408)

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ARNOLD & PORTER LLP
555 Twelfth Street, N.W.
Washington, DC 20004
Tel: 202-942-5000
Fax: 202-942-5999